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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,791	07/25/2003	Steve Bigus	ACS 64940 (2238D)	2675

24201 7590 04/30/2007

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EXAMINER	
ISABELLA, DAVID J	
ART UNIT	**PAPER NUMBER**
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/627,791	BIGUS ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11 and 20-34* is/are pending in the application.

4a) Of the above claim(s) *8-10,22,23 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,11,20,21,24 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Pre-Appeal Brief Conference

The request for a pre-appeal brief conference filed 3/8/2007 has been entered. Upon review of applicant's arguments, examiner concurs with some of applicant's arugments concerning the rejection in the final office action mailed 12/8/2006. Accordingly, the finality of the last office action has been withdrawn. In order to present a complete record, a non-final action appears below.

From the prosecution history, it is not clear as to which claims remain pending for consideration and which claims stand withdrawn as being directed to non-elected invention/species. To clarify the record, the following claim status is as follows:

Claims 2-4 and 12-19 are canceled.

Claims 8-10,22,23,31-34 have been withdrawn from consideration as being directed to non-elected species.

Claims 1,5-7,11,20,21,24-30 are pending for consideration.

Response to Arguments

Applicant's arguments filed 3/8/2007have been fully considered but they are not fully persuasive.

With respect to claims 25-30, applicant's arguments are correct, in that, Lenker '158 is silent with respect to the limitation of "the heat bond fails during expansion of the stent". Examiner has relied on Lenker'158, especially column 4, lines 20+ to support

the outstanding rejection. Upon further reading of Lenker'158, examiner agrees with applicant, that Lenker is silent as to the heat bond failing during expansion. However, the Examiner was interpreting the failure of the filaments would inherently encompass failure of the bonding between the filaments and the liner at the point(s) that the filaments fail.

With respect to Lenker, applicant has alleged that Lenker '161 is not prior art, in that it does not appear that the teachings relied on by the examiner is present in the parent application. Examiner respectfully disagrees with applicant interpretation of Lenker 6878161 which has priority back to Lenker 5843158. The subject matter relied upon in '161 is fully disclosed in Lenker'158. Applicant's attention is directed to columns 4,5,7,9,12 and 14. Accordingly, Lenker has an effective date back to February 6, 1996.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 11,20,21,24 and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenker (USPN 5843158).

Lenker ('158) discloses a catheter assembly for delivering an endoprosthesis within a body lumen with all the elements of claim 1. See Figure 2 for a catheter (30) and an endoprosthesis (10) disposed on an expandable member (48). See columns 6-8 for a biocompatible material being positioned on the endoprosthesis and preventing expansion of the endoprosthesis . See column 4, lines 20+ for the biocompatible material being configured to fail at an inflation pressure below the nominal inflation pressure of the expandable member.

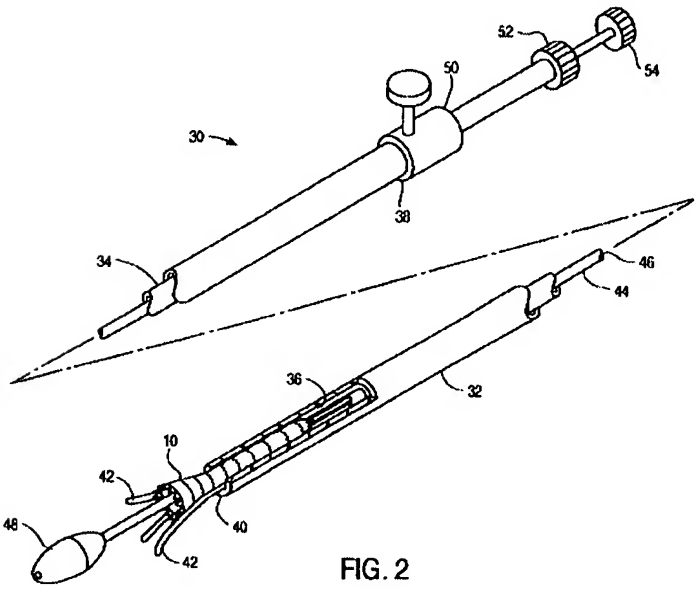

FIG. 2

Claim 5, see Figures 5A and 5B.

Claims 6 and 11. Lenker et al. ('158) teach a frangible filament (102) that is wrapped around and heat bonded to an endoprosthesis (100) in order to attach the filament to the endoprosthesis. See column 9, lines 42-45.

Claims 20 and 21, see column 4, lines 40+.

Claim 24, see column 4, lines 44+ for the endoprosthesis comprising a self-expanding stent.

A method for expanding the prostheses of the present invention is schematically shown in FIG. 4. An expansible prosthesis **70** has frame rings **72** sutured to an expansible liner **74**. Expansible liner **74** is formed from a material which expands plastically when subjected to a stress beyond a yield strength, and which remains expanded when the stress is removed, ideally exhibiting little or no spring back. By subjecting a cuff **76** to the expansive force of balloon **78**, the liner perimeter at a selected cross-section is increased. Advantageously, the expansion of expansible prosthesis **70** may be performed prior to shipping the prosthesis as a production step, at the surgical site prior to introduction of the prosthesis within the patient body, or preferably, after deployment of the prosthesis within a body lumen using an angioplasty-type balloon catheter or other minimally invasive expansion device.

Additional benefits can be realized by the application of radially expansive force from a balloon upon the liner of a deployed prosthesis. A balloon can be used to ensure full expansion of the liner from its compressed configuration, even when an inexpansible liner is supported by a self-expanding stent. The balloon may be inflated at one or more selected locations along the prosthesis, or may alternatively be sequentially applied along substantially the entire prosthetic lumen. Balloon expansion is particularly beneficial for smoothing wrinkles in the liner (or in the entire prosthesis), especially for ensuring that externally supported stent-grafts present a smooth prosthetic lumen in endovascular applications.

Frame rings **72** of expansible prosthesis **70** may comprise a material which is resilient, malleable, or some combination of the two. When resilient, frame rings **72** will preferably be radially restrained by expansible liner **74**, even after expansion of the liner to the predetermined limit. Such a liner-restrained stent-graft structure avoids any loosening of the fabric after balloon **78** has been removed, as more fully described in application Ser. No. 08/538,706 (Attorney Docket No. 16380-003800), the disclosure of which has previously been incorporated herein by reference. It should be pointed out that while such taut structures (in which self-expansion of the frame was restrained by the liner) were referred to as "liner-limited" in that earlier application, they will here be called "liner-restrained" to avoid confusion with the prosthesis expansion limiting structures of the present invention.

The cuff **76** of expansible prosthesis **70** will expand to a predetermined limit, here shown as a maximum diameter **80**. The expansion of expansible prosthesis **70** is generally then limited by a structural element of the prosthesis itself. In particular, once expanded to maximum diameter **80**, an element of either the liner **74** or the frame rings **72**, or in some embodiments, the interface between the two, impedes further expansion.

Claims 25-30 see rejection to corresponding claims supra.

Examiner has relied on Lenker'158, especially column 4, lines 20+ to support the outstanding rejection. Upon further reading of Lenker'158, examiner agrees with applicant, that Lenker is silent as to the heat bond failing during expansion. However, the Examiner was interpreting the failure of the filaments would inherently encompass failure of the bonding between the filaments and the liner at the point(s) that the filaments fail.

Claims 1, 5, 6, 11 and 24 rejected under 35 U.S.C. 102(e) as being anticipated by Lenker (USPN 6,878,161).

Lenker ('161) discloses a catheter assembly for delivering an endoprosthesis within a body lumen with all the elements of claim 1. See Figures 1A-2C for a catheter (126) and an endoprosthesis (110) disposed on an expandable member (125). See Figure 1A and column 6, lines 17-31 and 65-67 for a biocompatible material (123) being positioned on the endoprosthesis (110) and preventing expansion of the endoprosthesis (110). See column 7, lines 4-20 for the biocompatible material (123) being configured to fail at an inflation pressure below the nominal inflation pressure of the expandable member (125). Claim 5, see Figure 1A and column 6, lines 20-22 for the biocompatible material (123) comprising a filament that is wrapped around at least a portion of the endoprosthesis (110). Claims 6 and 11, see Figure 1A and column 6, lines 20-22 for the endoprosthesis having an open lattice configuration with open areas, and the filament

being threaded through the open areas. At least a portion of the filament is therefore positioned within the open areas. Claim 24, see column 5, lines 58-67 for the endoprosthesis comprising a self-expanding stent. See Figure 1A and column 6, lines 65-67 for the biocompatible material (123) providing an inward pressure on the stent to prevent expansion of the stent

Claims 20,21 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. ('158) in view of Solar (USPN 5,549,635, as cited in applicant's IDS).

Lenker et al. ('158) teach a frangible filament (102) that is wrapped around and heat bonded to an endoprosthesis (100) in order to attach the filament to the endoprosthesis. Solar teaches an endoprosthesis delivering catheter assembly, wherein a biocompatible material (40) is positioned on the endoprosthesis (10) and is configured to fail upon expansion of the expandable member (38). The biocompatible material (40) includes areas of varying strength in the form of perforations (42) in order for the biocompatible material (40) to fail only at those areas with the perforations and prevent the remaining portions of the biocompatible material (40) from being torn away from attachment to the expandable member (38). See Figures 4a-4c and column 6, lines 50-54 and column 7, lines 10-22. If not inherent in Lenker'158, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Solar to modify the filament (123) of Lenker ('158) by heat bonding the filament (123) to the endoprosthesis and including perforations. Upon inflation of the

expandable member (125), the filament (123) will fail only at those areas with the perforations while the remaining portions of the filament (123) that are heat bonded to the endoprosthesis (110) will be prevented from being torn away and becoming loose in the blood stream.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
4/13/2007